

REMARKS

Claims 21-36 are presently pending in the case. Reconsideration of the present case in view of the remarks herein is requested.

Claim rejections under 35 USC §102

Piper et al

The Examiner rejected claims 21, 24, 28, 32, 34 and 36 under 35 USC §102(b) as being anticipated by U.S. Patent 5,479,920 to Piper et al (hereinafter Piper et al). The rejection is traversed.

Piper et al does not anticipate independent claim 21, for example. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Claim 21 is to a device for controlling the delivery of an aerosolized active agent comprising, inter alia, a valve that provides a high flow resistance of at least $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ in the inhalation direction at the onset of the patient's inhalation. This positively recited feature is not disclosed by Piper et al. Piper et al does not disclose a valve that provides a high flow resistance of at least $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ in the inhalation direction at the onset of the patient's inhalation. Instead, Piper et al discloses a one-way valve (element 24) that provides a high flow resistance only in the exhalation direction (see column 4 lines 33-35). There is no high flow resistance in the inhalation direction in the Piper et al device as the valve (24) opens immediately upon inhalation. Since Piper et al does not disclose each and every feature set forth in claim 21, it does not anticipate the claim. Thus, the Examiner is respectfully requested to reconsider the language of claim Piper et al and withdraw the rejection thereof under 35 USC §102.

The Examiner's comments in the Final Office Action do not serve to establish Piper et al as an anticipatory reference. The Examiner posits that valve 24 of Piper et al satisfies the claim limitation because there is pressure built up within the system during a patient's exhalation. The Examiner's contention is incorrect for several reasons. First, Applicant's recitation in claim 21 relates to a structure feature of the claimed valve. That is, Applicant recites a high flow resistance in an inhalation direction. In contrast, valve 24 of Piper et al has a high flow resistance only in the exhalation direction. As recited in column 4 lines 22-24 of Piper: "A one-way (unidirectional) inhalation valve **24**, which is a conventional flapper valve or the like wherein the valve opens to permit flow in one direction [i.e. in the inhalation direction] but closes to prevent flow in the other direction [i.e. in the exhalation direction], is coupled to ..." [bracketed comments added]. Thus, the valve 24 of Piper et al is not a valve that includes the positively set forth structural feature of claim 21. Therefore, the Examiner's comments are not correct for this first reason.

Additionally, the Examiner position is incorrect because the Examiner ignores positively recited claim language in claim 21. Claim 21 recites that the valve provides a high flow resistance of at least $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$ in the inhalation direction. As discussed above, the Examiner relies on the presence of exhalation pressure to satisfy this limitation. However, there is no disclosure or suggestion in Piper et al that the "flow resistance" provided by the valve changes because of any exhalation pressure buildup. To the contrary, Piper et al specifically states that "when the patient inhales, valve **24** opens and pressure in the breathing circuit drops to a level below atmospheric pressure." Thus, the Examiner appears to be confusing "flow resistance" with "flow." Whether or not there is instantaneous flow through the valve 24 in Piper et al at the onset of inhalation has no relevance to what the flow resistance is at the onset of inhalation. Moreover, assuming *in arguendo* that the Examiner is correct and there is a slight increase in flow resistance through the valve 24 because of backside exhalation pressure, the Examiner has made no accounting for there being a flow resistance that is as high as the Applicant is claiming (i.e. at least $0.4 \text{ (cm H}_2\text{O)}^{1/2} / \text{SLM}$). This extremely high flow resistance would not be achieved by the situation described by the Examiner.

Thus, for these additional reasons, the Examiner's position taken in the Final Office Action is improper, and Applicant requests reconsideration.

Applicant requests withdrawal of the rejection of claim 21 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of the rejection of claim 24 which depends from claim 21 and is not anticipated by Piper et al for at least the same reasons as claim 21.

Piper et al also does not anticipate independent claim 28. Claim 28 is to a device comprising, inter alia, a valve that provides a high flow resistance in the inhalation direction at the onset of the patient's inhalation and which corresponds to a flow rate of about 15 liters per minute or less. Piper et al does not disclose a valve that provides a high flow resistance in the inhalation direction at the onset of inhalation. Instead, Piper et al's valve (24) opens at the onset of inhalation and provides little, if any, resistance to flow in the inhalation direction.

Applicant requests withdrawal of the rejection of claim 28 under 35 U.S.C. §102(b).

In addition, Piper et al does not anticipate independent claim 32. Claim 32 is to a device comprising, inter alia, a valve that is adapted to provide a first flow resistance in the inhalation direction at the onset of the patient's inhalation and that subsequently opens to provide a second flow resistance less than the first flow resistance. Piper et al does not disclose a valve that has a first flow resistance in the inhalation direction at the onset of inhalation that subsequently changes.

Applicant requests withdrawal of the rejection of claim 32 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of the rejection of claims 34 and 36 which depend from claim 32 and are not anticipated by Piper et al for at least the same reasons as claim 32.

Claim rejections under 35 USC 103(a)

Piper et al

The Examiner rejected claims 22, 23, 26, 27, 30, 31 and 33 under 35 USC §103(a) as being unpatentable over Piper et al. The rejection is traversed.

Claims 22 and 23 depend from claim 21, claims 26, 27, 30 and 31 depend from claim 28, and claim 33 depends from claim 32. Piper et al does not render independent claims 21, 28 and 32 unpatentable as discussed above. Thus, claims 22, 23, 26, 27, 30, 31 and 33 are allowable over Piper et al for at least the same reason as the claims from which they depend.

In addition, it would not have been obvious to one having ordinary skill in the art to modify Piper et al in a manner that would result in the invention set forth in the claims. There is no reason why one of ordinary skill would have been motivated to provide a valve that provides a high flow resistance at the onset of inhalation and that subsequently opens to provide a lower flow resistance. Such a modification is antithetical to the teachings of Piper et al where it is desired to allow for unrestricted inhalation flow.

For at least these reasons, claims 22, 23, 26, 27, 30, 31 and 33 are not properly rejectable under 35 USC §103(a) as being unpatentable over Piper et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the proposed modification could be applied—with a reasonable likelihood of success—to Piper et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined teachings in a manner that would result in the invention of claims 22, 23, 26, 27, 30, 31 and 33, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claims 22, 23, 26, 27, 30, 31 and 33 are allowable over the references cited.

Applicant requests withdrawal of the rejection of claims 22, 23, 26, 27, 30, 31 and 33 under 35 U.S.C. §103(a).

Piper et al and Carris

The Examiner rejected claims 25, 29 and 35 under 35 USC §103(a) as being unpatentable over Piper et al in view of U.S. Patent 4,227,522 to Carris (hereinafter Carris). The rejection is traversed.

Claims 25 and 29 depend from claim 21, and claim 35 depends from claim 32. Piper et al does not render independent claims 21 and 32 unpatentable as discussed above. Carris is not relied upon to make up for the deficiencies of Piper et al, nor does it. Since claims 21 and 32 are not rendered unpatentable by the combination of Piper et al and Carris, claims 25, 25 and 35 which depend therefrom are also not rendered unpatentable by the references.


Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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